

PROJECT CHARTER

| <p>Project Name: (1) Identify a genetic marker and develop an assay for disease X</p> <p>Team Leader: (3) Dr. D</p> | <p>Business/Location: (2) 460 West 12th Avenue, Columbus, OH 43210</p> <p>Champion: (4) Department Chair</p> | | | | | | | | | | | | | | | | | | | | | | | | | |
|--|--|---|---|--|-------------|--------|--------|---|--|--|---|---|--|--|---|--|--|--------------------------------|--|--|--|--|--|---|--|--|
| <p>Project Description/Mission: (5) Discover/establish association between biomarker and disease X, develop assay, test performance</p> | | | | | | | | | | | | | | | | | | | | | | | | | | |
| <p>Problem Statement: (6) Early detection and treatment of disease X can help prevent serious medical problems later in life. An assay is needed to screen newborns just after birth to identify disease X in order to begin early treatment and improve patient outcomes</p> | | | | | | | | | | | | | | | | | | | | | | | | | | |
| <p>Business Case: (7) Health: When correctly diagnosed at an early age, patients receive relatively inexpensive pills; this can lead to better quality of life and fewer complications. OSU and the investigative team: Development of a cost-effective assay provides a commercialization opportunity.</p> | | | | | | | | | | | | | | | | | | | | | | | | | | |
| <p>Deliverables: (8) 1. Cell culture 2. Expression analysis 3. candidate gene approaches, 4. mouse studies, 5. selection of biomarker, 6. selection of assay platform, 7. determine sample, 8. recruit patients, 9. test performance, 10. refine as needed, 11. determine effects and compare to existing tests, 12. disseminate results</p> | <p>Goals/Metrics: (9) Years 1-2 Discover/establish association; Year 2 Develop assay based on identified biomarker, Years 3-5 Test performance of defined assay in targeted populations</p> | | | | | | | | | | | | | | | | | | | | | | | | | |
| <p>Process & Owner: (10) Biomarker and assay development process - Dr. D, process owner</p> | | | | | | | | | | | | | | | | | | | | | | | | | | |
| <p>Project Scope Is: (11) discovery through performance testing and dissemination</p> <p>Project Scope Is Not: Treatment of disease X, commercialization process</p> | | | | | | | | | | | | | | | | | | | | | | | | | | |
| <p>Key Customers: (12) patients, medical teams, insurance companies, pharmaceutical companies</p> | <p>Expectations: (13) cost-effective assay with high performance</p> | | | | | | | | | | | | | | | | | | | | | | | | | |
| <p>Milestones: (14) Project Start: 30 days after funding received</p> <p>Project Completion: Five years</p> | <p>Completion Dates: (15) Years 1-2 Association studies completed Year 3 Assay developed Years 3-5 Performance testing completed</p> | | | | | | | | | | | | | | | | | | | | | | | | | |
| <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th rowspan="2" style="width: 30%;">Expected Business Benefits: (16)</th> <th colspan="2" style="text-align: center;">Quantify</th> <th rowspan="2" style="text-align: left;">Explanation</th> </tr> <tr> <th style="width: 15%;">1-Time</th> <th style="width: 15%;">Annual</th> </tr> </thead> <tbody> <tr> <td><input checked="" type="checkbox"/> Hard Cost</td> <td></td> <td></td> <td rowspan="6">See attached budget for hard costs; opportunity cost - team and facility unavailable for alternative projects</td> </tr> <tr> <td><input checked="" type="checkbox"/> Soft Cost</td> <td></td> <td></td> </tr> <tr> <td><input checked="" type="checkbox"/> Revenue</td> <td></td> <td></td> </tr> <tr> <td><input type="checkbox"/> Speed</td> <td></td> <td></td> </tr> <tr> <td><input type="checkbox"/> Compliance (CMS, JCAHO, AHA Guidelines)</td> <td></td> <td></td> </tr> <tr> <td><input checked="" type="checkbox"/> Intangible (Reputation)</td> <td></td> <td></td> </tr> </tbody> </table> | | Expected Business Benefits: (16) | Quantify | | Explanation | 1-Time | Annual | <input checked="" type="checkbox"/> Hard Cost | | | See attached budget for hard costs; opportunity cost - team and facility unavailable for alternative projects | <input checked="" type="checkbox"/> Soft Cost | | | <input checked="" type="checkbox"/> Revenue | | | <input type="checkbox"/> Speed | | | <input type="checkbox"/> Compliance (CMS, JCAHO, AHA Guidelines) | | | <input checked="" type="checkbox"/> Intangible (Reputation) | | |
| Expected Business Benefits: (16) | Quantify | | Explanation | | | | | | | | | | | | | | | | | | | | | | | |
| | 1-Time | Annual | | | | | | | | | | | | | | | | | | | | | | | | |
| <input checked="" type="checkbox"/> Hard Cost | | | See attached budget for hard costs; opportunity cost - team and facility unavailable for alternative projects | | | | | | | | | | | | | | | | | | | | | | | |
| <input checked="" type="checkbox"/> Soft Cost | | | | | | | | | | | | | | | | | | | | | | | | | | |
| <input checked="" type="checkbox"/> Revenue | | | | | | | | | | | | | | | | | | | | | | | | | | |
| <input type="checkbox"/> Speed | | | | | | | | | | | | | | | | | | | | | | | | | | |
| <input type="checkbox"/> Compliance (CMS, JCAHO, AHA Guidelines) | | | | | | | | | | | | | | | | | | | | | | | | | | |
| <input checked="" type="checkbox"/> Intangible (Reputation) | | | | | | | | | | | | | | | | | | | | | | | | | | |
| <p>Team Members: (17) Dr. D (PI), Lillian (Co-PI), Chase (Clinician/Co-I), David (research scientist), Marie (genetic counselor) Daniel (graduate student), Jay (mouse technician), Anna (lab manager)</p> | | | | | | | | | | | | | | | | | | | | | | | | | | |
| <p>Expected Resource Needs (Internal/External): (18) See attached budget</p> | | | | | | | | | | | | | | | | | | | | | | | | | | |
| <p>Risk Assessment: (19) Risk of not meeting timelines and milestones; risk of non delivery on assay development and non performance of assay; risk that budget is inadequate</p> | | | | | | | | | | | | | | | | | | | | | | | | | | |
| <p>Prepared By: (20) David, research scientist</p> | <p>Date (Last Revision): (21) Today</p> | | | | | | | | | | | | | | | | | | | | | | | | | |

KEY:

- 1) Enter Project Name
- 2) Enter Business Unit, Location, Division, or other identifier.
- 3) Individual responsible for assembling team, driving the project and accountable for recommendations and results of team's effort. Assembles team and drives problem solving process and agenda. Assesses team needs and team member performance.
- 4) Individual responsible for directing efforts of the team. Works with team leader to develop strategies, set direction and goals, acquire necessary resources and resolve barriers or conflicts. Monitors progress of team and makes adjustments as appropriate.
- 5) Describe the project that the team is expected to complete. What is the team expected to accomplish or deliver.
- 6) Describe the problem or opportunity prompting this project activity - in customer terms. Outline what the team is expected to develop or remedy.
- 7) Why undertake this project vs. some other activity?
- 8) List the project deliverables - the process or product changes to be implemented.
- 9) Qualify or quantify the desired outcome of the team's process or recommendations.
- 10) Describe the process affected by this project and identify the process owner.
- 11) Qualify or describe the geographic, organizational, physical or other boundaries of the team's reach to reach an solution.
- 12) Who are the various internal or external customers of the team's process or impacted by the team's recommendations.
- 13) To the extent known, what outcomes or metrics do the customers expect?
- 14) List the steps that the team is expected to complete as part of the project.
- 15) Indicate preliminary dates for completion of the project milestones.
- 16) What are the expected business benefits, both tangible and intangible? Identify the categories impacted with a checkmark, then quantify if possible. Distinguish between one-time benefits and ongoing annual benefits. Provide a description to explain the projected benefits and their calculation.
- 17) List the participants on the team.
- 18) List the nature, time period and intensity of any auxiliary resources likely to be needed as the team progresses in its work. Estimate cost of any external resources required, e.g. consultants
- 19) Describe any material risks associated with the project
- 20) Who created/revised the Charter?
- 21) Note the date of creation and any revisions. Revisions should be approved and signed-off by the Project Champion.